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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/934,973	08/22/2001	Timothy P. Croughan	98A9-USC1 Croughan	8353

25547 7590 02/11/2003

PATENT DEPARTMENT
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EXAMINER

KRUSE, DAVID H

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/934,973

Applicant(s) *File Copy*

CROUGHAN, TIMOTHY P.

Examiner

David H Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 62-73 and 75-81 is/are pending in the application.
- 4a) Of the above claim(s) 63,65,67,69,71-73,76,78 and 80 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 62,64,66,68,70,75,77,79 and 81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>1</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 62, 64, 66, 68, 70, 75, 77, 79 and 81, in Paper No. 4, filed 14 January 2003 is acknowledged.
2. Claims 63, 65, 67, 69, 71-73, 76, 78 and 80 are withdrawn from further consideration pursuant to 37 CFR § 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 4.
3. This application contains claims 63, 65, 67, 69, 71-73, 76, 78 and 80 drawn to an invention nonelected with traverse in Paper No. 4. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR § 1.144). See MPEP § 821.01.

Information Disclosure Statement

4. The information disclosure statement filed 22 August 2001 has been considered, a signed copy is attached hereto.
5. Parent Application 09/830,194 on the PTO-1449 form, page 1, has been considered, the citation has been crossed out because an application is not a proper reference to print on the face of a Patent.

Terminal Disclaimer

6. The Examiner notes that Applicant has filed a Terminal Disclaimer, disclaiming the terminal part of any patent granted in the instant application that would extend beyond any US Patent issued on co-pending Application 09/830,194.

Claim Objections

7. Claims 64, 66, 69, 70, 77, 79 and 81 are objected to because of the following informalities: The phrase "A rice plant" should read -- The rice plant -- to denote that the claims is further limiting the plant at claim 62, for claims 64, 66, 69 and 70, and the plant at claim 75, for claims 77, 79 and 81. Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

9. Claims 62, 64, 66, 69, 70 and 81 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 62 is indefinite because after both subsections (a) and (b), the conjunction "and" is used making the claim unclear if one is to select (a) and (b); or (a) and (c); or (a) and (b) and (c). Hence, it is unclear what the metes and bounds of the claimed invention are.

At claim 62(b), line 1, the phrase "is a derivative of a rice plant" is indefinite because there are many ways to derive a rice plant, hence it is unclear what the metes and bounds of the claim are. Similarly, at 62(d), lines 2 and 4, the terms "derivative" and "derivatives" render the claim indefinite.

At claim 81, line 1, the phrase "said plant is a derivative of the plant" is indefinite because there are many ways to derive a rice plant, hence it is unclear what the metes and bounds of the claim are.

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At claim 81, line 2, the phrase “the herbicide resistance characteristics of the plant” is indefinite because it is unclear if this limitation requires that the “characteristics” come from the deposited line ‘75295’ or can come from any other rice plant having the characteristics.

10. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 62, 64, 66, 68, 70, 75, 77, 79 and 81 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims a herbicide-resistant rice plant that is resistant to inhibition by at least one AHAS inhibiting herbicide, is a “derivative” of a rice plant obtained by exposing rice plants to mutation-inducing conditions and expresses a functional AHAS that is resistant to inhibition by said herbicide. In addition, Applicant claims a herbicide-resistant rice plant having a first and second resistant AHAS wherein said first and second resistant AHAS's are not identical, and a rice plant that is a “derivative” of the plant with ATCC accession number 75295 and has the herbicide resistance characteristics of the plant with ATCC accession number 75295.

Applicant describes herbicide-resistant rice plants produced by EMS mutagenesis with resistance to herbicides that inhibit the function of a non-mutant

AHAS enzyme (pages 8-13 of the specification). Applicant also describes specific herbicide-resistant rice plants produced having been deposited with the ATCC (see pages 9 and 11 of the specification).

Applicant does not describe what specific mutations have occurred in the exemplified herbicide-resistant rice plants or how to distinguish the exemplified herbicide-resistant rice plants or progeny thereof from other herbicide-resistant rice plants that are mutant.

Hence, it is unclear from the instant specification that Applicant was in possession of the invention as broadly claimed.

See *Brenner v. Manson*, 383 U.S. 519 (1966), which states "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point--where specific benefit exists in currently available form--there is insufficient justification for permitting an applicant to engross what may prove to be a broad field."

See also, MPEP § 2163 which states that the claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. In the instant case, Applicant does not describe the structure of the invention by which one of skill in the art could recognize Applicant's claimed invention, other than the function of the herbicide-resistant rice plant. In addition, at claim 81, Applicant

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admits that Applicant does not understand the resistance mechanism the produces the function within the deposited '75295' herbicide-resistant rice plant (see page 24, 1st paragraph of the specification, and page 8, last paragraph of WO 97/41218).

12. Claims 62, 64, 66, 68, 70, 75, 77, 79 and 81 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel plants. Since the plant(s) is(are) essential to the claimed invention it(they) must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the plant is not so obtainable or available, the requirements of 35 USC § 112 may be satisfied by a deposit of the plant. A deposit of 2500 seeds of each of the claimed embodiments is considered sufficient to ensure public availability. The specification does not disclose a repeatable process to obtain the plant and it is not apparent if the plant is readily available to the public. It is noted that applicants have deposited the plant(s) but there is no indication in the specification that all of the requirements have been met (see below).

(a) If the deposit was made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed

upon the granting of the patent., would satisfy the deposit requirement made herein (see 37 CFR § 1.808).

(b) If the deposit was not made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

- (i) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (ii) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (iii) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
- (iv) a test of the viability of the biological material at the time of deposit (see 37 CFR § 1.807); and,
- (v) the deposit will be replaced if it should ever become inviable.

13. Claims 62, 64, 66, 68, 70, 75, 77, 79 and 81 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant claims a herbicide-resistant rice plant that is resistant to inhibition by at least one AHAS inhibiting herbicide, is a “derivative” of a rice plant obtained by exposing rice plants to mutation-inducing conditions and expresses a functional AHAS that is resistant to inhibition by said herbicide. In addition, Applicant claims a herbicide-resistant rice plant having a first and second resistant AHAS wherein said first and second resistant AHAS's are not identical, and a rice plant that is a “derivative” of the plant with ATCC accession number 75295 and has the herbicide resistance characteristics of the plant with ATCC accession number 75295.

Applicant teaches a method of isolating herbicide-resistant rice plants produced by EMS mutagenesis with resistance to herbicides that inhibit the function of a non-mutant AHAS enzyme (pages 8-13 of the specification). Applicant also teaches specific herbicide-resistant rice plants produced by said method having been deposited with the ATCC (see pages 9 and 11 of the specification).

Applicant does not teach what specific mutations have occurred in the exemplified herbicide-resistant rice plants or how to distinguish the exemplified herbicide-resistant rice plants or progeny thereof from other herbicide-resistant rice plants that are mutant.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art,

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the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Applicant teaches specific mutant rice plants that have resistance to herbicides that inhibit plant AHAS enzymes (see pages 9 and 11). Applicant does not teach what these mutations are in the exemplified herbicide-resistant rice plants. Applicant only teaches the phenotype of the exemplified herbicide-resistant rice plants. Applicant teaches a group of lines on page 11, 3rd paragraph, of the specification that have lower level of resistance than those deposited with the ATCC, where Applicant admits that the mechanism(s) of resistance is not known in these specific rice lines. Applicant admits that the resistance mechanism of the rice lines has not been fully characterized (see page 7, 3rd paragraph). The art teaches that P450 enzymes and glutathione transferase enzymes can also be involved in resistance to herbicides such as imazethapyr (see Barrett 2000, pp. 25-37 in Herbicides and their Mechanisms of Action, Cobb and Kirkwood eds., CRC Press, Boca Raton, Florida, see especially page 30). Hence, it would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to screen through a myriad of herbicide-resistant rice plants that are a "derivative" of a rice plant obtained by exposure to mutation-inducing conditions and expresses at least one functional AHAS enzyme that is resistant to inhibition by at least one herbicide that normally inhibits AHAS activity, in addition to identifying two plants expressing non-identical AHAS enzymes that are herbicide-resistant to produce the herbicide-resistant rice plant at claims 75, 77, 79 and 81.

Claim 81 is not enabled because the claim can be read to encompass a rice plant that is a "derivative" of ATCC accession number 75295, but the "herbicide resistance characteristics of the plant with ATCC accession number 75295" can be introduced from another rice plant. Since Applicant only teaches one of skill in the art that the "herbicide resistance characteristics" of the deposited plant does not appear to be an AHAS mutation, one of skill in the art would have required undue trial and error experimentation to duplicate the "herbicide resistance characteristics" in another rice plant and produce the claimed "derivative" rice plant.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

15. Claims 62, 64, 66, 68 and 70 are rejected under 35 U.S.C. § 102(b) as being anticipated by Terakawa *et al* 1992 (Japan. J. Breed. 42:267-275).

Terakawa *et al* disclose a herbicide-resistant rice plant wherein growth of said rice plant is resistant to at least one herbicide that normally inhibits AHAS enzymes (syn. ALS used by Terakawa *et al*), is a derivative of a rice plant obtained by exposing rice plants to mutation-inducing conditions, expresses a functional AHAS enzyme that is

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resistant to inhibition by at least one herbicide that normally inhibits AHAS enzymes and is not a "derivative" of the plant with ATCC accession number 97523 (see Table 4 on page 271). Terakawa *et al* disclose that said rice plant is resistant to at least one sulfonylurea herbicide, and without evidence to the contrary, would inherently be resistant to at least one imidazolinone herbicide also. Hence, Terakawa *et al* have previously disclosed all of the claim limitations.

Claim 70 has been included in this rejection because the process of producing the herbicide-resistant rice plant disclosed by Applicant does not adequately distinguish those plants claimed by Applicant from those of Terakawa *et al*. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

Claim Rejections - 35 USC § 102/103

16. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. Claims 62, 64, 66, 68, 70, 75, 77, 79 and 81 are rejected under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Croughan (U.S. Patent 5,773,704, published 30 June 1998, filed 29 April 1996).

Croughan discloses a herbicide-resistant rice plant wherein growth of said rice plant is resistant to at least one herbicide that normally inhibits AHAS enzymes, is a

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derivative of a rice plant obtained by exposing rice plants to mutation-inducing conditions, expresses a functional AHAS enzyme that is resistant to inhibition by at least one herbicide that normally inhibits AHAS enzymes and a process of making same, said herbicide-resistant rice plant having been deposited as ATCC accession number 97523 (see columns 7 and 8). Croughan also discloses that other genes encoding herbicide resistant AHAS enzymes may be used and introduced by transforming rice plants (see column 10, 3rd paragraph). Croughan discloses that synergism from combinations of two resistant mechanisms can be introduced using the deposited herbicide-resistant rice plant, ATCC access number 75295 (see columns 8-10).

Croughan does not specifically teach rice plants having a first and a second non-identical herbicide-resistant AHAS enzyme.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention to use the teachings of Croughan to make other herbicide-resistant rice plants comprising a herbicide resistant AHAS enzyme and to use the taught rice plant deposited as ATCC accession number 75295 to incorporate multiple resistance mechanisms into a progeny herbicide-resistant rice plant. In addition, crossing one herbicide-resistant rice plant with a herbicide resistant AHAS enzyme with another herbicide-resistant rice plant comprising another, different herbicide resistant AHAS enzyme would have been obvious to one of ordinary skill in the art. One of ordinary skill in the art would have had a reasonable expectation of success in producing other herbicide-resistant rice plants having a herbicide-resistant AHAS enzyme given the teachings of Croughan, and would have had a reasonable

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expectation of success in passing the herbicide-resistance on to progeny rice plants as claimed.

18. Claims 62, 64, 66, 68, 70, 75, 77 and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Croughan 1994 (Louisiana Agriculture 37(3): 25-26) in view of Terakawa *et al* 1992 (Japan. J. Breed. 42:267-275).

Croughan (1994) teaches a method of producing herbicide-resistant rice plants that are resistant to AHAS inhibiting herbicides and an isolated, herbicide-resistant rice plant (see page 26, center column).

Croughan (1994) does not specifically teach that the isolated herbicide-resistant rice plant has a herbicide-resistant AHAS enzyme.

Terakawa *et al* teaches a method of producing herbicide-resistant rice plants that are resistant to AHAS inhibiting herbicides and an isolated, herbicide-resistant rice plant (see pages 269-272). Terakawa *et al* also teach that the mechanism of resistant is a mutant AHAS enzyme (see page 272).

Hence, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention to use the teachings of Terakawa *et al* to modify the teachings of Croughan (1994) to identify a herbicide-resistant rice plant having one or more herbicide-resistant AHAS enzymes. Terakawa *et al* teach that plants have multiple isozymes and that mutation of any of these isozymes can result in herbicide-resistance (see page 273, 3rd paragraph). Given the success of both Croughan and Terakawa in producing herbicide-resistant rice plants having resistant to herbicides that

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inhibit AHAS enzyme, one of ordinary skill in the art would have had a reasonable expectation of success.

Double Patenting

19. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

20. Claims 62, 64, 66, 68, 70, 75, 77, 79 and 81 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 5,773,704. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the issued Patent teach a herbicide-resistant rice plant that has the herbicide resistance characteristics of the plant deposited with ATCC accession number 97523. Because the issued claims do not limit the number of generations away from said deposited plant, the herbicide-resistant rice plant of the instant claims would be obvious, because one of ordinary skill in the art would not be able to distinguish the "derivative" plant of the patented herbicide-resistant rice plant from the "derivative" plant of the instant claims.

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Conclusion

21. No claims are allowed.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read "Amy Nelson", with a stylized flourish at the end.

**AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600**

David H. Kruse, Ph.D.
6 February 2003